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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,528	03/23/2001	Roger D. Kamm	0492611-0375 (MIT-8802)	5331
7590	01/27/2004		EXAMINER	MATHEW, FENN C
C. Hunter Baker, M.D., Ph.D. Choate, Hall & Stewart 53 State Street Exchange Place Boston, MA 02109			ART UNIT	PAPER NUMBER
			3764	
			DATE MAILED: 01/27/2004	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/815,528	Applicant(s) KAMM ET AL.
	Examiner	Art Unit
	Fenn C Mathew	3764

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 05 November 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-30,32 and 34-61 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-30,32 and 34-61 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) The translation of the foreign language provisional application has been received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). ____ .
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ . 6) Other: ____ .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 5, 2003 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-30, 32, 34, and 54-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis (U.S. 6,620,116). Referring to claim 1, Lewis teaches the method including the steps of attaching a compression apparatus to a body part of a patient suffering a disease characterized by low blood flow (circulatory disease), and applying graded sequential compression (col. 4, lines 61-65) to the body part of the

patient using the compression apparatus, wherein the compression delivers a desired pressure range. Although Lewis does not specifically disclose the maximum pressure ranging from 75mm Hg to 300 mm Hg, Lewis does disclose the device capable of a range between 5.2 mm Hg to 362 mm Hg (col. 5, lines 39-40). The claimed maximum pressure range falls within ranges taught by Lewis. It would be obvious to the skilled artisan to choose appropriate maximum pressures based on suitability for the intended function.

5. Regarding claim 2, Lewis does not explicitly disclose the patient having a wound. The feature of using compression methods to treat wounds with compression is well known in the art, and would have been obvious to the skilled artisan.

6. Referring to claims 3-8, 12, and 14-18, it would have been obvious to the skilled artisan that Lewis's device would be able to perform the recited function since Lewis's device has the same structure claimed, and is used to treat circulatory disorders.

7. Referring to claims 9-11, Lewis teaches pressure ranges which include the claimed pressure ranges. The skilled artisan would select the appropriate the appropriate maximum pressures based on suitability for diseases treated.

8. Referring to claim 13, Lewis discloses graded sequential compression timed with the cardiac cycle (col. 4, lines 23-25).

9. Referring to claims 19-21, Lewis discloses the device attached to an extremity of a patient including a patient's leg or arm (col. 3, line 67 – col. 4, line 1).

10. Referring to claims 22-25, Lewis discloses a series of inflatable bladders that can be filled with gas or liquid. (Lewis discloses bladders are filled to a fixed volume, thus it meets the requirement of an inflatable bladder).

11. Referring to claim 26, Lewis discloses use of flexible stretchable bands (col. 10, lines 45-54) under variable tension (inherently tension varies based on how tightly the band is wound).

12. Referring to claims 27-29, Lewis teaches in col. 3, lines 1-5, that the method is used to peripheral vascular, cardiovascular, and coronary artery diseases.

13. Referring to claim 30, Lewis discloses the claimed structure; therefore it would be obvious to the skilled artisan to use the claimed invention to treat diabetes.

14. Referring to claims 32 and 34, Lewis discloses methods for treating disease including attaching an apparatus for delivering positive (constriction) and negative (relaxing) pressure to a body part of a patient, and applying negative pressure to the body part, and applying graded sequential compression to the body part using the apparatus. Although Lewis does not explicitly disclose that the device is used for wound healing, the structural limitations are met, and the recited method steps may be performed.

15. Referring to claim 54, Lewis discloses an apparatus for compressing a part of a patient's body including at least one flexible band (cuff) a means for mounting the band on the body part (col. 8, lines 44-49), and a control means for controlling the tension in the band thus the band's resulting pressure on the body.

16. Referring to claims 55-61, limitations drawn to specific speed ranges of waves, time periods for sequential compression, and pressure differences between the distal and proximal regions are considered matters of obvious design choice well within the knowledge of the skilled artisan, as the skilled artisan would choose parameters based on suitability for the intended function of treating a specific condition or disease.

17. Claims 35-39, 40, 44, 47, 49, and 51-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zheng (U.S. 5,997,540) in view of Lewis. Zheng teaches a device having a plurality of sequentially inflatable balloons (col. 8, lines 39-42), and a computer 7. In column 5, lines 15-24 and column 14, lines 22-24, Zheng discloses a blood oxygen detector, pulse oximeter and blood pressure detector. Zheng further discloses cooling means (21) and a mounting means within the cuff for mounting the cuff to the body (figure 4C). Zheng fails to teach the specific maximum pressures and graded sequential pressure. Lewis teaches the desirability of graded sequential pressure in an analogous device in column 4, line 61 – column 5, line 30. Furthermore Lewis teaches pressure ranges including the claimed pressure ranges. It would have been obvious to one having ordinary skill in the art at the time of invention to provide the device of Zheng with graded sequential pressure as taught by Lewis in order to limit constriction in more sensitive areas (i.e. groin) while providing heavier pressure in areas better capable of receiving such pressure (i.e. ankles) in order to reduce injury while maintaining peak effectiveness. Furthermore, the desired pressure ranges used would also be obvious to the skilled artisan as the skilled artisan would choose appropriate pressure ranges based on their suitability for the disease being treated.

18. Referring to claim 39, Lewis teaches that it is advantageous to provide an EKG detection mechanism in order to correlate sequential pressure based on a patient's heart waves.

19. Claims 35, 41-46, 48 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cariapa (U.S. 5,437,610) in view of Lewis. Cariapa teaches a hydraulic system including sequentially compressible bladders (figs. 1-2) being attached to a body part of a patient. Cariapa fails to teach the claimed pressure ranges. Lewis teaches pressure ranges including the claimed pressure ranges, and furthermore teaches that the device is useful for treating edema (col. 1, lines 23-27). Therefore it would have been obvious to one skilled in the art at the time of invention to utilize pressures in the range of Lewis in order to treat disease. Furthermore, Cariapa fails to teach graded sequential pressure as defined by the applicant. Lewis teaches the desirability of graded sequential pressure in an analogous device in column 4, line 61 – column 5, line 30. It would have been obvious to one having ordinary skill in the art at the time of invention to provide the device of Cariapa with graded sequential pressure as taught by Lewis in order to limit constriction in more sensitive areas (i.e. groin) while providing heavier pressure in areas better capable of receiving such pressure (i.e. ankles) in order to reduce injury while maintaining peak effectiveness.

20. Regarding claims 41-43, note the withdrawal pump (28) and reservoir (30).

21. Regarding claims 44-46, Cariapa teaches a VELCRO (94) mounting means or control means) but lacks buttons, snaps, elastic bands, or zippers. The feature of choosing different mounting means such as buttons, snaps, elastic bands, or zippers is

considered as an obvious design choice since such mounting means are well known in the art.

Response to Arguments

22. Applicant's arguments, with respect to Drawing objections and rejections under 35 U.S.C. 112 have been fully considered and are persuasive. The objections have been withdrawn.

23. Applicant's arguments with respect to claims 1-30, 32, 34-61 have been considered but are moot in view of the new ground(s) of rejection. Lewis teaches graded sequential pressure as defined and claimed by the applicant. Furthermore, Lewis teaches pressure ranges including the ranges claimed by applicant.

Conclusion

24. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Waldridge U.S. 6,645,165

Wasserman U.S. 6,558,338

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fenn C Mathew whose telephone number is (703) 305-2846. The examiner can normally be reached on Monday - Friday 9:00am - 5:30pm.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Art Unit: 3764

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.



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January 14, 2004

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